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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,489	11/14/2003	Hau H. Duong	67456-5012-US02	1026

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,489	DUONG ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-25* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,17,18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on October 30, 2007 have been entered. The claims pending in this application are claims 11-25 wherein claims 14-16 and 19 have been withdrawn due to species election mailed on May 17, 2007. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on October 30, 2007.

Specification

2. The disclosure is objected to because of the following informalities: (1) since applications 08/873, 596 and 08/911,589 now are US Patent Nos.6,068,008 and 6,232,062 respectively, applicant is required to update these information in pages 1 and 2 of the specification; (2) PCT/US98/12430, PCT/US98/12082, PCT/US99/10104, PCT/US99/01705, and PCT/US 99/01703 in pages 2 and 5 of the specification should be published now. However, there are no "WO" numbers for these PCT applications in pages 2 and 5 of the specification; (3) PCT/US98/12430, PCT/US98/12082, PCT/US99/01705, and PCT/US 99/01703 in page 33 of the specification should be published now. However, there are no "WO" numbers for these PCT applications in page 33 of the specification; (4) since application 09/135,183 was abandoned, it is

unclear how this abandoned application can be incorporated by reference; (5) since application 09/135,183 was abandoned while application 09/295,691 now is US Patent No. 6,942,771, applicant is required to update these information in page 33, second paragraph of the specification; (6) since application 09/134,158 now is US Patent No.5,917,759, applicant is required to update this information in page 72 of the specification; (7) PCT/US 97/20014 in pages 73, 74, 76, 79, and 80 of the specification should be published now. However, there is no "WO" number for this PCT application in pages 73,74, 76, 79, and 80 of the specification; and (7) there are several nucleotide sequences having more than 10 nucleotides in page 122 of the specification. However, there are no SEQ ID NOs for these nucleotide sequences in page 122 of the specification.

Appropriate correction is required.

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Direct the reply to the undersigned.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13, 17, 18, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 is rejected as vague and indefinite. Since the claim does not indicate how the presence of the characteristic waveform in the output waveform is correlated with the presence of said analytes in the assay complex, it is unclear why presence of the characteristic waveform in the output waveform can be an indication of the presence of said analytes in the assay complex. Please clarify.

7. Claim 12 or 13 recites the limitation "the act" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word "act" in claim 11. Please clarify.

8. Claim 25 is rejected as vague and indefinite. Since claim does not indicate how electron transfer between the electron transfer moiety and the electrode is correlated with the presence of said analytes in the assay complex, it is unclear why electron transfer between the electron transfer moiety and the electrode can be an indication of the presence of said analytes in the assay complex. Please clarify.

9. Claim 11 or 25 is rejected as vague and indefinite. Since the claim does not indicate how difference between the output waveform of an array complex in the presence of a target analyte and the output waveform of an array complex in the absence of the target analyte, it is unclear how analyzing the output waveform of an array complex in the presence of a target analyte can be used as an indication of the presence of a target analyte. Please clarify.

Response to Arguments

In page 8, third paragraph bridging to page 9, last paragraph of applicant's remarks, applicant argues that, as disclosed by page 94, second full paragraph of the specification, "the frequency response of the system in the absence of a target is very low at particular frequencies. Therefore, 'any response at a particular frequency will show the presence of the assay complex.' In this way, by 'analyzing the output waveform for the presence of the characteristic waveform' according to claim 11, one can obtain 'an indication of the presence of said target analytes.' As such, claim 11 and claims dependent therefrom are not indefinite. In claim 25, the assay complex comprises 'a target analyte, a capture binding ligand and an electron transfer moiety.' The capture binding ligand serves to anchor the target analytes to the electrode surface. Specification, p. 5, ¶ 2. '[T]he presence of the ETM near the electrode surface is dependent on the presence of the target analyte.' *Id.* Electron transfer can then be initiated between the ETM and the electrode. '[B]y detecting electron transfer, the presence or absence of the target analyte is determined.' *Id.* Chronocoulometry, as recited in claim 25, is merely one type of analysis that can be applied to the output waveform to detect electronic transfer. *Id.* at p. 101, ¶ 1. Since detecting electron transfer through chronocoulometry provides an indication of the presence of target analytes, claim 25 is not indefinite".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because, although page 94, second full paragraph of the specification describes that "[I]n one embodiment, detection utilizes a single measurement of output signal at a single frequency. That is, the frequency response of the system in the absence of target sequence, and thus the absence of label probe containing ETMs, can be previously determined to

be very low at a particular high frequency. Using this information, any response at a particular frequency, will show the presence of the assay complex. That is, any response at a particular frequency is characteristic of the assay complex. Thus, it may only be necessary to use a single input frequency, and any changes in frequency response is an indication that the ETM is present, and thus that the target sequence is present", page 94, second full paragraph, page 4, second paragraph, and page 101, first paragraph of the specification suggested by applicant do not indicate that the presence of a target analyte can be determined without comparing difference between the output waveform of an array complex in the presence of a target analyte and the output waveform of an array complex in the absence of the target analyte.

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 16, 2008

FRANK LU
PRIMARY EXAMINER

Application No.: 10/114,489

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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